UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 28, 2007

MEMORANDUM

SUBJECT: Review of "*Determination of Removal Efficiency of Permethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol*"

FROM: Seyed Tadayon, Chemist
Reregistration Branch 3
Health Effects Division (7509P)

THRU: Jeff Evans, Biologist
Chemistry Exposure Branch (CEB)
Health Effects Division (7509P)

TO: [redacted]
Special Review and Reregistration Division (7508P)

DP Barcode: 336761
PC Code: 109701
MRID Number: 461886-17

Attached is a review of the MRID 461886-17 "*Measurement of Transfer of Permethrin and Piperonyl Butoxide (PBO) From Hand Surface Using Isopropyl Alcohol*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the total amount of PY and PBO residues that can be removed from the hand surface following a single application of the pre-fill batch fogger formulation containing 0.783% and 1.47% pyrethrin and piperonyl butoxide, respectively.

Five qualified subjects participated in the study. The formulated product was diluted in isopropyl alcohol (IPA) to nominal concentrations of 1, 10.1 and 30.1 µg PYI (i.e., three pyrethin I esters) in 25 or 35 µL, applied directly to the washed hands of the test subjects, and allowed to dry for 30 minutes. Following the drying time, the hands of the subjects were then wiped with two dressing sponges wetted with 5 mL of IPA.

Total hand residues were calculated by the study author for each hand of the test subjects. Residues were reported for PYI and PBO. PYI residues removed from the hands ranged from 0.795 to 1.04 µg/sample with a mean value of 0.879 ± 0.08 µg/sample at the 1.0 µg/sample application rate, ranged from 8.61 to 10.9 µg/sample with a mean value of 10.1 ± 0.76 µg/sample at the 10.1 µg/sample application rate, and ranged from 23.1 to 33.4 µg/sample with a mean value of 30.0 ± 2.91 µg/sample at the 30.1 µg/sample application rate. PBO residues removed from the hands ranged from 2.29 to 2.87 µg/sample with a mean value of 2.59 ± 0.21 µg/sample at the 3.34 µg/sample application rate, ranged from 27.6 to 29.9 µg/sample with a mean value of 28.9 ± 0.79 µg/sample at the 33.5 µg/sample application rate, and ranged from 63.7 to 89.9 µg/sample with a mean value of 83.0 ± 7.50 µg/sample at the 100 µg/sample application rate. The percent of the applied concentration removed from the test subject's hands by the dressing sponges wetted with IPA was 95.8 ± 10.0% for PYI and 82.2 ± 6.7% for PBO. Versar did not have to correct the data, as all field fortification recoveries were >90%.

Concurrent laboratory control dressing sponge samples were fortified with the formulated product. Overall average recoveries were 103.6 ± 4.59% for PYI and 93.6 ± 8.82% for PBO. For field fortification, overall average recoveries were 107.7 ± 10.31% for PYI and 100.3 ± 5.16% for PBO.

Samples analyzed in this study were used to measure the removal efficiency of PY and PBO from bare hands to which a known amount of formulated product had been applied. The study calculated residues based on the amount removed from the hand by the dressing sponges. The percent of the applied concentration that was removed from the test subject's hands by the dressing sponges wetted with IPA was 95.8 ± 10.0% for PYI and 82.2 ± 6.7% for PBO. Versar did not have to correct the data, as all field fortification recoveries were >90% (Table A).

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300 Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines

Table A. Summary of PYI and PBO Dressing Sponge Results from Hand Sampling

Replicate	Sample Concentration (µg/sample)		Measured Residue µg/sample)		Average Amount Recovered (µg/sample)		Percent Recovered (%)		Overall Percent Recovered ± Std. Dev. (%)	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
11R			0.812	2.55						
11L			0.830	2.38						
21R			0.939	2.85						
21L			0.850	2.69						
31R			0.825	2.47						
31L			0.795	2.51						
41R			0.803	2.29						
41L			0.930	2.42						
51R			1.04	2.87						
51L	1.00	3.34	0.970	2.84	0.879	2.59	87.9	77.5		
110R			8.61	28.7						
110L			9.43	28.5						
210R			10.8	29.4						
210L			10.6	29.5						
310R			9.56	27.6						
310L			10.7	29.9						
410R			9.75	28.3						
410L			10.0	29.4						
510R			10.9	27.9						
510L	10.1	33.5	10.7	29.6	10.1	28.9	100.0	86.2		
130R			30.9	85.9						
130L			31.1	85.8						
230R			33.1	85.4						
230L			33.4	89.9						
330R			28.7	79.7						
330L			30.3	83.4						
430R			30.7	88.9						
430L			30.1	86.4						
530R			28.2	80.5						
530L	30.1	100	23.1	63.7	30.0	83.0	99.5	83.0	95.8 ± 10.0	82.2 ± 6.7

Versar inc.

MEMORANDUM

TO:	Margarita Collantes	cc:	110082.4000.001.01
FROM:	Traci Brody/Linda Phillips		
DATE:	March 4, 2004		
SUBJECT:	Review of "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol*" (Project #: 00-046-PY01)		

This report reviews a study entitled "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol.*" The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study.

Reviewers: Traci Brody/Linda Phillips **Date: March 4, 2004**

STUDY TYPE: Active Transfer; Hand

TEST MATERIAL: The test substance was a pre-fill batch formulation similar to that for an indoor fogger formulation developed by the McLaughlin Gormley King Company (MGK) containing the active ingredients: Pyrethrin (0.783% ai wt/wt) and Piperonyl Butoxide (1.47% ai wt/wt).

SYNONYMS: Pyrethrin = PY
Piperonyl Butoxide = PBO

CITATION:

Author/Study Director:	Sami Selim, Ph.D.
Title:	*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol*
Report Date:	August 26, 2002
Testing Facility:	Toxcon Health Sciences Research Centre, Inc. 9607 - 41 Avenue Edmonton, Alberta Canada T6E 5X7
Analytical Facility:	Enviro-Test Laboratories/XENOS Division Unit 13 - 210 Colonnade Road Nepean, Ontario Canada K2E 7L5
Identifying Codes:	Toxcon Study No.: 00-046-PY01 Xenos Project No.: XEN00-42

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol*"submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the total amount of PY and PBO residues that can be removed from the hand surface following a single application of the pre-fill batch fogger formulation containing 0.783% and 1.47% pyrethrin and piperonyl butoxide, respectively.

Five qualified subjects participated in the study. The formulated product was diluted in isopropyl alcohol (IPA) to nominal concentrations of 1, 10.1 and 30.1 µg PYI (i.e., three pyrethin I esters) in 25 or 35 µL, applied directly to the washed hands of the test subjects, and allowed to dry for 30 minutes. Following the drying time, the hands of the subjects were then wiped with two dressing sponges wetted with 5 mL of IPA.

Total hand residues were calculated by the study author for each hand of the test subjects. Residues were reported for PYI and PBO. PYI residues removed from the hands ranged from 0.795 to 1.04 µg/sample with a mean value of 0.879 ± 0.08 µg/sample at the 1.0 µg/sample application rate, ranged from 8.61 to 10.9 µg/sample with a mean value of 10.1 ± 0.76 µg/sample at the 10.1 µg/sample application rate, and ranged from 23.1 to 33.4 µg/sample with a mean value of 30.0 ± 2.91 µg/sample at the 30.1 µg/sample application rate. PBO residues removed from the hands ranged from 2.29 to 2.87 µg/sample with a mean value of 2.59 ± 0.21 µg/sample at the 3.34 µg/sample application rate, ranged from 27.6 to 29.9 µg/sample with a mean value of 28.9 ± 0.79 µg/sample at the 33.5 µg/sample application rate, and ranged from 63.7 to 89.9 µg/sample with a mean value of 83.0 ± 7.50 µg/sample at the 100 µg/sample application rate. The percent of the applied concentration removed from the test subject's hands by the dressing sponges wetted with IPA was 95.8 ± 10.0% for PYI and 82.2 ± 6.7% for PBO. Versar did not have to correct the data, as all field fortification recoveries were >90%.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- The test product was not identified and no product label was provided.
- None of the test conditions (temperature, barometric pressure, ventilation) were reported.
- The study author calculated residues based on the amount removed from the hand by the dressing sponges. The size of the test subject's hands were not reported to determine the amount removed per surface area.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10 (d)1(A), (B), or (C). The Study Report indicated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR Part 160), with the following exception: information recorded on subject entry, exit and hand inspection forms was not entered and/or corrected according to GLP Regulations.

GUIDELINE OR PROTOCOL FOLLOWED:

The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group B: 875.2300. The study was conducted following Xenos and

Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 00-046-PY01). The study protocol was approved by study management in December 2000.

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation: An unidentified pre-fill batch fogger formulation similar to that for an indoor fogger, developed by McLaughlin Gormley King Company (MGK); contains Pyrethrin (0.783 % ai) and Piperonyl butoxide (1.47% ai) as the active ingredients.

Lot/Batch # formulation: 0110-1
Formulation guarantee: Certificate of Analysis provided.
CAS #(s):Pyrethrin: 8003-34-7
Piperonyl butoxide: 51-03-6
Other Relevant Information: Toxcon ID No.: PY01T006

2. Relevance of Test Material to Proposed Formulation(s):

PY and PBO are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was a pre-fill batch formulation similar to that of an indoor fogger formulation developed by McLaughlin Gormley King Company (MGK). The name and label for the test product was not provided with the study.

B. Study Design:

There were six amendments to and two deviations from the protocol. The amendments were as follows: 1) the Study Director changed to Dr. Sami Selim; 2) the method of analysis was Xenos Analytical Method XAM-66 instead of Method XAM-60; 3) the entire study was repeated according to the protocol, 35 µL of the high level spike solution was be used, and the dressing sponges wetted with IPA were placed inside glass jars prior to spiking; 4) on-site medical assessments were conducted on each subject pre- and post-exposure; 5) Toxcon batch numbers and study subject number were assigned to the test formulation and test subjects; and 6) Toxcon maintained a reserve sample of the test substance. The deviations from the protocol were as follows: 1) on day 1 of the study, subject 323 left the facility after the hand-wiping procedure and did not complete the hand washing procedure and post-exposure medical assessment and 2) the total palmar surface area was not calculated as part of this study.

1. Site Description:

Test locations: Not applicable to the study. The test product was applied directly to the hands of five test subjects.
Meteorological Data: Not reported.

Ventilation/Air-Filtration: Not reported.

2. Surface(s) Monitored:
Room(s) Monitored: Not applicable to this study.
Room Size(s): Not applicable to this study.
Types of Surface(s): Hand surfaces (palms) of five test subjects.
Surface Characteristics: The subjects' hands were washed with liquid Ivory soap, rinsed with tap water, and dried with a paper towel approximately 5 minutes before application of the formulated product.
Areas sprayed and sampled: The diluted formulated product was applied directly to the palms of the washed hands of the test subjects. The hands were sampled with dressing sponges wetted with IPA to determine the amount of compound that could potentially be transferred from the hand to mouth.
Other products used: None
3. Physical State of Formulation as Applied : Liquid

4. Application Rates and Regimes:
Application Equipment: The diluted formulation was pipetted directly to the hands using 25 µL and 10 µL Wiretrol micropipettes.
Application Regime: Each test concentration of the diluted product was applied to the washed palms of 10 hands (5 test subjects) and allowed to dry for 30 minutes before being wiped with the dressing sponges.
Application rate(s): The formulation was diluted with IPA to a nominal concentration of 1 µg, 10 µg, and 30 µg of PYI per 25 µL or 35 µL of isopropyl alcohol.
Equipment Calibration Procedures: Not applicable to this study.
Was total deposition measured? Not applicable to this study.

D. Sampling:

Surface Areas Sampled: The palms of five test subjects (male and female) were sampled; however, the surface area measurement of their hands was not reported.

Replicates per sampling interval: Both hands of the five test subjects were sampled at three application rates (10 replicates per application level; 30 total replicates).

Number of sampling intervals: There was one sampling interval for each concentration. Sampling was conducted approximately 30 minutes after the test substance was applied to the hands.

Method and Equipment:The hand wipe was conducted using two 4" x 4" 6-ply dressing sponges.

Sampling Procedure(s): Deposition coupons -Not applicable to this study.

Hand residues- The removal of the test substance was conducted 30 minutes following application of the test substance. Five test subjects (ten hands) were used. The hand wipe consisted of wiping the palm of the hand with 4" x 4" 6-ply dressing sponges. About 5 mL of IPA was added to each dressing sponge prior to use. Two dressing sponges were used per hand. The hand wipe procedure is described in Toxcon SOP M-023.

3. Sample Handling and Storage:

The dressing sponges were placed in separate pre-labeled 180 mL amber glass jars with Teflon lids and stored in the dark at less than -10EC until being shipped to the analytical laboratory. Sample storage and shipment were conducted according to Toxcon Nos. G-022 *Storage of Test Samples and Analytical Extracts* and G-028 *Test Sample Distribution to a Contract Laboratory*. Samples were shipped to the analytical laboratory by airfreight with priority overnight delivery. Samples were shipped in an insulated cooler with dry ice.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Dressing sponges: Residues were extracted once from the dressing sponges by sonication and mechanical shaking at room temperature with ethyl acetate. The total ethyl acetate extracts were rotary evaporated to dryness. All sample extracts were brought to volume in acetonitrile and analyzed for PBO using HPLC/Fluorescence detection. An aliquot of the acetonitrile solution was collected, evaporated to dryness under nitrogen and reconstituted in toluene. The toluene extract was cleaned-up using an Isolute silica SPE cartridge. The cleaned up samples were reconstituted in toluene before analysis for PYI using GC/ECD. PYI was quantified as the sum of three PYI esters (i.e., Pyrethrin I (P-I), Cinerin I (C-I), and Jasmolin I (J-I).

B. Detection methods:

A Varian Saturn 2000 GC/MS system was used consisting of a Model 8200 autosampler, a 3400 GC and a ^{63}Ni ECD (15 mCi). An HPLC system was used consisting of a Shimadzu pump (LC-10ADvp), a Varian 9300 autosampler, a Cera Column Heater 250 and a Shimadzu fluorescence monitor (RF-10AXL). See Table 1 for details on the GC conditions.

Table 1. Gas Chromatographic Conditions

GC Column	Precolumn:	DB-1, 1 m x 0.53 mm x 0.25 µm	
	Analytical Column:	SPB-1, 30 m x 0.32 mm x 0.25 µm	
Temperatures	Inlet:	Initial:	120EC, hold 0.10 min.
		Program:	120-280EC at 20EC/min., hold 5 min.
	Column:	Initial:	90EC, hold 2.0 min.
		Program 1:	90-140EC at 20EC/min.
		Program 2:	140-190EC at 2EC/min.
		Program 3:	190-280EC at 50EC/min., hold 5 min.
	Detector:	330EC	
Injection Volume	2.0 µL		
Rate	0.5 µL/sec. on-column		
Head Pressure	20 psi		
Septum Purge	6.7 mL/min.		
Carrier Gas Flow Rate	5.4 mL/min.		
ECD makeup	46.3 mL/min.		
Approximate Retention Times	C-I ~ 23.9 min. J-I ~ 27.0 min. P-I ~ 27.8 min.		

Table 1a. Liquid Chromatographic Conditions

Column	Precolumn:	Zorbax RX-C8, 4.6 x 12.5 mm
	Analytical Column:	Zorbax RX-C8, 4.6 x 250 mm
Column Temperature	30EC	
Mobile Phase	Isocratic: 70% acetonitrile 30% water	

Flow Rate	1.0 mL/min.
Injection Volume	20 µL
Fluorescence Detection	Exitation: 288 nm; Emission: 345 nm
Approximate Retention Time	PBO: ~8.6 min.

D. Method Validation:

The analytical methods were validated in a previous study. The Study Report states that validation data for the limits of quantitation (LOQ) were taken from Xenos report XEN01-12. LOQs are reported for PYI, PY, and PBO and vary according to the percent composition of the formulation used (see Table 2).

Table 2. Validated LOQ Values

Matrix	Formulation	PYI	PY	PBO
Dressing Sponges	100 µg	0.440 µg	0.784 µg	1.58 µg

Instrument performance and calibration: The GC/ECD and HPLC/Fluorescence calibration solutions were prepared from the formulation by dilution in toluene and acetonitrile, respectively. Five GC/ECD instrument calibration solutions were prepared at concentrations of 5.00 ng/µL, 10.0 ng/µL, 20.0 ng/µL, 30.0 ng/µL, and 40.0 ng/µL. Five HPLC instrument calibration solutions were prepared at concentrations of 10.0 ng/µL, 20.0 ng/µL, 40.0 ng/µL, 60.0 ng/µL, and 80.0 ng/µL. The GC/MS and HPLC responses were determined using the prepared calibration standards to perform a linear regression analysis.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control dressing sponge samples were fortified with the formulated product. One set of samples was fortified at the LOQ and the others were fortified at either 2.5x, 5x, 50x or 100x the LOQ. Results from the laboratory fortified samples are summarized in Table 3. The recovery of the low level spike for PYI was 105.4% versus 105.7% at the high level. The recovery of the low level spike for PBO was 91.4% versus 93.9% at the high level. Overall average recoveries were 103.6 ± 4.59% for PYI and 93.6 ± 8.82% for PBO.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

	Fortification Level (µg)[1]		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
Matrix	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge			0.468	1.44			103.6	93.6	4.59	8.82	4.43	9.43
			0.443	1.43								
			0.482	1.04								
			0.453	1.40								
	0.441	1.47	0.479	1.41	105.4	91.4						
	1.10	3.68	1.05	3.65	95.5	99.2						

	Fortification Level (µg)[1]		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	2.21	7.35	2.19	6.71	99.1	91.3						
			22.3	75.9								
	22.1	73.5	23.8	66.7	104.3	97.0						
	44.1	147	46.6	138	105.7	93.9						

1 Fortification levels were 1x, 2.5x, 5x, 50x and 100x the LOQ.

Field Fortification: Diluted formulated product (25 µL or 35 µL) was directly applied to a triplicate set of two dressing sponges that had been wetted with IPA to yield an amount of 1, 10.1, and 30.1 µg PYI (ie., 2.3x, 23x, and 68x the LOQ) per each set of dressing sponges. These samples were placed in a glass jar and stored frozen prior to shipment to the analytical laboratory. Field fortification results are summarized in Table 4. Overall average recoveries were 107.7 ± 10.31% for PYI and 100.3 ± 5.16% for PBO.

Table 4. Summary of Field Fortification Recoveries.

Matrix	Fortification Level (ug/sample)[1]		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std Dev.		%RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing Sponge	1.00	3.34	0.993	3.38	104.1	97.5	107.7	100.3	10.31	5.16	9.58	5.14
			1.05	3.20								
			1.08	3.19								
	10.1	33.5	9.47	31.8	103.5	97.5						
			10.4	33.7								
			11.5	32.5								
	30.1	100	37.5	106	115.5	106.0						
			36.5	110								
			30.3	102								

1 Fortification levels were at 2.3x, 23x, and 68x the LOQ.

Control Samples: Each analytical set included one laboratory and one field control. All concurrent laboratory and field control samples for the dressing sponges had no detectable PYI residues. Four of the five laboratory controls had apparent PBO residues that were <½ LOQ. PBO was also detected in the four field control samples, but the residues were not quantifiable and corresponded to <½ the LOQ

Storage Stability:The field fortified samples were analyzed after a maximum frozen storage period of 30 days. The Study Report stated that this confirmed the stability of the residues over this time period.

V. RESULTS

Field fortification recoveries were all >90%; therefore, the data did not need to be corrected. Resides were reported for both PYI and PBO at application rates of 1.00, 10.1, and 30.1 µg PYI and 3.34, 33.5, and 100 µg PBO applied to the hands.

A. Alpha Cellulose and Deposition of Formulation:

Not applicable to this study.

B. Hand Residues

Total hand residues were calculated by the study author for each hand of the test subjects. Residues are reported for PYI and PBO. PYI residues removed from the hands ranged from 0.795 to 1.04 µg/sample with a mean value of 0.879 ± 0.08 µg/sample at the 1.0 µg/sample application rate, ranged from 8.61 to 10.9 µg/sample with a mean value of 10.1 ± 0.76 µg/sample at the 10.1 µg/sample application rate, and ranged from 23.1 to 33.4 µg/sample with a mean value of 30.0 ± 2.91 µg/sample at the 30.1 µg/sample application rate. PBO residues removed from the hands ranged from 2.29 to 2.87 µg/sample with a mean value of 2.59 ± 0.21 µg/sample at the 3.34 µg/sample application rate, ranged from 27.6 to 29.9 µg/sample with a mean value of 28.9 ± 0.79 µg/sample at the 33.5 µg/sample application rate, and ranged from 63.7 to 89.9 µg/sample with a mean value of 83.0 ± 7.50 µg/sample at the 100 µg/sample application rate. The percent of the applied concentration removed from the test subject's hands by the dressing sponges wetted with IPA was 95.8 ± 10.0% for PYI and 82.2 ± 6.7% for PBO. Versar did not have to correct the data, as all field fortification recoveries were >90%.

VI. CONCLUSION

Samples analyzed in this study were used to measure the removal efficiency of PY and PBO from bare hands to which a known amount of formulated product had been applied. The study author calculated residues based on the amount removed from the hand by the dressing sponges. The percent of the applied concentration that was removed from the test subject's hands by the dressing sponges wetted with IPA was 95.8 ± 10.0% for PYI and 82.2 ± 6.7% for PBO. Versar did not have to correct the data, as all field fortification recoveries were >90%.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review

the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines.

- The test product was not identified and no product label was provided.
- None of the test conditions (temperature, barometric pressure, ventilation) were reported.
- The study author calculated residues based on the amount removed from the hand by the dressing sponges. The size of the test subject's hands were not reported to determine the amount removed per surface area.

Table 5. Summary of PYI and PBO Dressing Sponge Results from Hand Sampling

Replicate	Sample Concentration (µg/sample)		Measured Residue (µg/sample)		Average Amount Recovered (µg/sample)		Percent Recovered (%)		Overall Percent Recovered ± Std. Dev. (%)	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
11R			0.812	2.55					95.8 ± 10.0	82.2 ± 6.7
11L			0.830	2.38						
21R			0.939	2.85						
21L			0.850	2.69						
31R			0.825	2.47						
31L			0.795	2.51						
41R			0.803	2.29						
41L			0.930	2.42						
51R			1.04	2.87						
51L	1.00	3.34	0.970	2.84	0.879	2.59	87.9	77.5		
110R			8.61	28.7						
110L			9.43	28.5						
210R			10.8	29.4						
210L			10.6	29.5						
310R			9.56	27.6						
310L			10.7	29.9						
410R			9.75	28.3						
410L			10.0	29.4						
510R			10.9	27.9						
510L	10.1	33.5	10.7	29.6	10.1	28.9	100.0	86.2		
130R	30.1	100	30.9	85.9	30.0	83.0	99.5	83.0		
130L			31.1	85.8						
230R			33.1	85.4						
230L			33.4	89.9						
330R			28.7	79.7						
330L			30.3	83.4						
430R			30.7	88.9						
430L			30.1	86.4						

530R			28.2	80.5						
530L			23.1	63.7						

APPENDIX A

Compliance Checklist for "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using DSS and IPA*"

Compliance Checklist for "Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) from Hand Surfaces Using DSS and IPA"
GUIDELINE 875.2300
INDOOR SURFACE RESIDUE DISSIPATION
POSTAPPLICATION

1. *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case_by_case basis.* This criterion does not apply to this study. There was no mention of metabolites, breakdown products or other contaminants.

2. *Indoor surface residue studies should be conducted under ambient conditions similar to those encountered during the intended use season, and should represent reasonable worst case conditions.* It is not known whether this criterion was met. Conditions in the area where the hands were treated was not reported.

3. *Ambient conditions (i.e., temperature, barometric pressure, ventilation) should be monitored.* This criterion was not met. None of the test conditions were reported.

4. *The end use product should be applied by the application method recommended on the label. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included.* This criterion does not apply to this study. Samples analyzed in this study were used to measure the removal efficiency of pyrethrin and piperonyl butoxide from bare hands that had been fortified with the formulated product.

5. *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases.* This criterion does not apply to this study.

6. *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion does not apply to this study; only one application to the hands was made at each concentration. The hands were wiped with the dressing sponges in between applications.

7. *Indoor surface residue (ISR) data should be collected from several different types of media (e.g., carpeting, hard surface flooring, counter tops, or other relevant materials).* This criterion does not apply to this study. The objective of this study was to measure the removal of pyrethrin and piperonyl butoxide from bare hands that had been fortified with the formulated product.

8. *Sampling should be sufficient to characterize the dissipation mechanisms of the compound (e.g., three half_lives or 72 hours after application, unless the compound has been found to fully dissipate in less time; for more persistent pesticides, longer sampling*

periods may be necessary). Sampling intervals may be relatively short in the beginning and lengthen as the study progresses. Background samples should be collected before application of the test substance occurs. This criterion does not apply to this study.

9. *Triplicate, randomly collected samples should be collected at each sampling interval for each surface type.* This criterion was met.

10. *Samples should be collected using a suitable methodology (e.g., California Cloth Roller, Polyurethane Roller, Drag Sled, Coupons, Wipe Samples, Hand Press, vacuum cleaners for dust and debris, etc.) for indoor surfaces.* This criterion was met.

11. *Surface sampling should be conducted in conjunction with air sampling. Enough duplicate air samples should be taken in a room to establish a dissipation curve*. This criterion does not apply to this study. The test substance was not sprayed, rather it was applied by pipette directly to the test subject's hands.
12. *Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analysis. Information on storage stability should be provided.* This criterion was met.

13. *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided.* This criterion was met.

14. *Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low_level and high_level fortification. These fortifications should be in the range of anticipated residue levels in the field study.* This criterion was met.

15. *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion was met. Field fortification recoveries were all >90%; therefore, data correction was not required.

16. *Indoor surface residues should be reported as mg per m^2 or cm^2 of surface sampled. Distributional data should be reported, to the extent possible.* This criterion was not met. However, the known concentration of the formulated product was applied directly to the test subject's hands; therefore, the size of the test subject's hands may not be a factor.

17. *Reported residue dissipation data in conjunction with toxicity data should be sufficient to support the determination of a reentry interval.* This criterion does not apply to this study.